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ADMITTED IN DC ONLY

June 8, 2018

Re: UMB Bank, N.A., as Trustee v. Sanofi, 15 Civ. 8725 (S.D.N.Y.) (GBD) (RWL)

Dear Magistrate Judge Lehrburger:

We are pleased that Sanofi has agreed to produce the documents itemized in Mr. Neuwirth's June 7, 2018 letter to Your Honor. *See* ECF No. 200. It should not have taken a motion from the Trustee (ECF No. 197) to obtain this information, nor should Sanofi be able to limit its production to only that which it wishes to provide.<sup>1</sup>

Let us be clear what happened. For purely mercenary reasons and contrary to the advice of its own clinical experts, Sanofi delayed developing Lemtrada as a treatment for PPMS. Sanofi did this knowing that such a study would improve, if not guarantee, the chances of achieving the Approval Milestone and PSM #1. Seven years too late, its CEO now says Lemtrada will be developed in PPMS, but on a timeline that insures that no CVR Holder will benefit.

Limiting the Trustee's access to documents of Sanofi's choosing allows Sanofi to control the narrative and blocks legitimate discovery. Sanofi's proposed list is deficient.

- It contains only the final, sanitized versions of documents. The Trustee is entitled to the deliberative documents showing why GLD52 was abandoned in favor of Lemtrada.
- Sanofi refuses to produce the most recent marketing, strategic or long range plans that put
  the development of Lemtrada in PPMS in proper context. How Sanofi, from a marketing
  and commercial perspective, intends to capitalized on its newly found interest in PPMS is

<sup>&</sup>lt;sup>1</sup> It was not until its written response to the Trustee's motion that Sanofi indicated whether it would provide any documents at all. Given that discovery was to close at the end of June, it seems only reasonable that the Trustee filed this motion.

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-2-

as important as the decision to do the study itself, and shows what Sanofi could have done in a timely manner to achieve the milestones in the CVR Agreement.

- Sanofi refuses to produce its communications with the FDA. The Trustee believes that such discussions will confirm that PPMS is an "unmet need" and could lead to a label extension for Lemtrada worth billions of dollars a year.
- Sanofi refuses to produce the Integrated Development Plan for Lemtrada in PPMS, a core document usually created for such a development program.
- The Trustee sought documents as to whether the timing of the PPMS trial was influenced by the CVR Agreement expiration date. In this regard, it is instructive that Sanofi has not offered any email communications at all.

The Trustee's motion sought a list of documents by category.<sup>2</sup> These were crafted to be narrow and reasonably focused. The issues presented by Sanofi's recent change of heart with respect to Lemtrada are important. An order consistent with that list is fair. Any other result allows Sanofi to avoid legitimate discovery and impermissibly control the factual record.

Respectfully submitted,

Michael B. Welss

Hon. Robert W. Lehrburger United States Magistrate Judge Southern District of New York 500 Pearl Street New York, New York 10007-1312

Via ECF

cc: Counsel of Record

 $<sup>^2</sup>$  These are the seven categories of documents specified in my email annexed as Exhibit A to Sanofi's June 7, 2018 letter (ECF No. 200) to Your Honor.